DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

July 29, 1999

Dear Medical Device Manufacturer:

The purpose of this letter is to inform you that on July 14, 1999, the Federal Communication Commission (FCC) unanimously adopted a Notice of Proposed Rule Making (NPRM) to allocate spectrum for wireless medical telemetry. The Food and Drug Administration (FDA) strongly supports the steps the FCC has taken to address the potential problem of electromagnetic interference (EMI) with wireless medical telemetry. The FDA will continue to work with device manufacturers and users to assure that the effects of EMI on wireless medical telemetry are minimized. **We, therefore, encourage you to provide your comments to the FCC regarding this NPRM.** For a copy of the NPRM and recent developments regarding this NPRM, you can visit the FCC web site for up-to-date information:

http://www.fcc.gov/oet/dockets/et99-255/

Since our records indicate that you may be marketing a medical device that utilizes wireless telemetry technology, the recommended changes proposed by the FCC may impact the operation of devices marketed by your company. If this is the case, FDA strongly recommends that you evaluate the FCC's NPRM in detail and respond to the Notice in a timely manner. When the FCC's rule is finalized, the FDA is committed to working with device manufacturers and users to facilitate the migration to these frequencies as quickly as possible in a least burdensome manner.

FDA has been an active partner with users, manufacturers, and FCC to address the potential problem of EMI with wireless medical telemetry. In our letter sent to your company, dated March 15, 1999, we informed you of the ongoing efforts that are taking place between the American Hospital Association (AHA), the FDA, and the FCC. As a result of this effort, a Medical Telemetry Task Force was formed by the AHA which includes members from the clinical community, the medical device industry, the FDA, and the FCC. On April 16, 1999, the AHA task force submitted its recommendations, for addressing the telemetry EMI concerns, to the FCC. These recommendations have formed the basis for the FCC NPRM.

In order to address the telemetry EMI concerns, the FCC is planning to establish a new Wireless Medical Telemetry Service (WMTS) for low-power, wireless medical telemetry. This initiative marks the first time in the U.S. that wireless medical telemetry will have primary or co-primary status for use of the airways. The NPRM proposes two options for the WMTS frequencies:

> frequency bands 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz , or
> frequency bands 608-614 MHz, and 1391-1400 MHz.

In addition, service rules are being proposed for coordination of the use of these frequencies to minimize problems among users. The NPRM seeks comments on the frequencies, service rules, and coordination.

Finally, we are in the process of developing a guidance document to assist wireless medical telemetry manufacturers in meeting any FDA regulatory requirements that may apply to devices that utilize a new WMTS. When this guidance document is complete, it will be disseminated for comment and use.

If you have any questions regarding these issues, please contact Thinh X. Nguyen at (301) 443-8262, ext. 162.

Sincerely yours,

Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and Radiological Health